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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,927

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Rolf U. Halden

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,927	Applicant(s) HALDEN, ROLF U.	
	Examiner Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18, 21, 22 and 50 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/01/2006 Updated</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response and remarks filed 16 March 2010 to the Office Action with Non-Final Rejection mailed 17 September 2009 is acknowledged and entered.

Claims Status

2. Claims 1-10 and 23-49 remain cancelled.
3. Claim 50 has currently been added.
4. Claims 11-22 and 50 are pending and are examined on merits.

Information Disclosure Statement

5. In view of Applicant's assertion made in Remarks filed 16 March 2010 (Page 4, Lines 15-19), the Information Disclosure Statement filed 01 August 2006 has been re-considered and duly initialed PTO FORMS SB08 are enclosed with the instant Office Action.

Claim Rejections - 35 USC §102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 11-13 are rejected under 35 U.S.C. §102(b) as anticipated by Scholin et al., (US Patent 6,187,530 B1, Applicants' IDS item AB) as evidenced by Osman San, 2003. Micro structural characterization of capillary filter produced from a high silica-containing glaze. Materials Letters, Volume 57, Pages 2189– 2192, and U.S. Patent 4,784,768, cited in rebuttal to argument.

In response to the rejection of Claims 11-13 under 35 U.S.C. §102(b) as anticipated by Scholin et al., the argument presented is that cited art includes a filter disc not an array of capillary microcosm. As evidence, Applicant recites citations from the Scholin Patent that the sample is placed on the filter by a syringe and the water is pulled through the filter disc. With said citations. Applicant additionally provides the dictionary meaning of "capillary" to add

emphasis to Applicant's arguments cited *supra*. On the basis of said arguments, Applicant concludes that the Scholin Patent does not teach a capillary microcosm and therefore, said prior art patent does not anticipate Applicants invention claimed in Claims 11-13 as currently presented (See, Remarks filed 16 March 2010, Page 4, Lines 25-27; Page 5, Lines 4-30; Page 6, Lines 4-30 and Page 7, Lines 4-15).

As currently presented, the invention claimed in Claims 11-13 is understood as shown in EXHIBIT1 below:

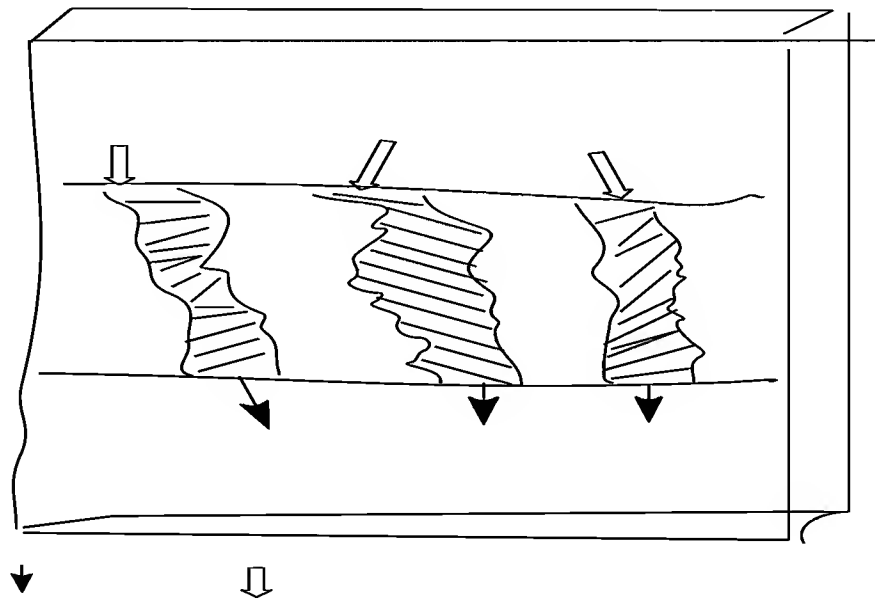


EXHIBIT 1: A DIAGRAMMATIC REPRESENTATION OF A FILTER DISC.

The three dimensional rectangle is the housing for the disc;

The patterned middle area depicts the microstructure within the thickness of the disc;

The arrows represent the flow of sample and water through the disc; and

Irregular structures represent the capillary structure present within the thickness of the filter disc.

Accordingly, the filter disc per Scholin et al's teachings is in housing, when the water or sample containing microorganisms is deposited on said filter, the sample passes through the capillaries intrinsically present within the thickness of said disc and the water from the sample flows through the disc and is discharged. The microorganisms present in the sample are held within the surfaces of said capillaries. Since multiple capillaries of said type are present in any given filter disc said filter disc is a microcosm. Please note, Claims 11-13 are drawn to a method to characterize the cells in an environment, by:

- (a) placing a collecting device in the environment, said device comprising
 - “(i) an array of capillary microcosm for trapping cells; and
 - (ii) a housing surrounding the array having an opening to controllably permit cells from the environment to access the array”

The broadest interpretation of the claim is “an environment”, “an automated device to collect microorganisms”, “an array of capillary microcosm contained in a housing having openings” without defining what said microcosm is constituted of, and the claims do not describe any capillary action for filtration. As discussed in Office Action mailed 17 September 2009 (e.g., pages 2-3, item 7); Scholin et al., clearly teach all of said features (see, e.g., Column 4, Lines 15-50) and additional features claimed in Claim 11b-11d, 12 and 13.

Scholin et al., further teach that depending on need, any type of filter may be applied (Column 4, Lines 33-34). Additionally, the pertinent art teaches a number of filter discs that are clearly comprised of capillaries (See, e.g., Osman San, 2003. Micro structural characterization of capillary filter produced from a high silica-containing glaze. Materials Letters, Volume 57, Pages 2189– 2192, Figure 6 and U.S. Patent 4,784,768, e.g., Column 4, Lines 31-66). In each of said filters, each capillary is a microcosm.

Therefore, the Scholin et al., reference is deemed to anticipate the cited claims.

Applicant's arguments cited *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at pages 2-3, item 7 of the Office Action mailed 17 September 2009 and for the additional reasons as discussed and explained in the preceding paragraphs. Therefore, rejection of 11-13 under 35 U.S.C. §102(b) as anticipated by Scholin et al., in the Office Action mailed 17 September 2009 is maintained and adhered to.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 11-18, 21-22 and newly presenting Claim 50 are rejected under 35 U.S.C. §103 (a) as obvious over combined teachings from Scholin et al., (US Patent 6,187,530 B1, Applicants' IDS item AB) in view of Kosher et al. (US Patent 6,730,517 B1) and further in view of Isola et al (1997. MALDI-TOF Mass Spectrometric Method for Detection of Hybridized DNA oligomers. Analytical Chemistry, Volume 73, Pages 2126-2131, Applicants' IDS, item CB).

To the rejection cited *supra*, in the response filed 16 March 2010; the presented argument is (See, Response at Page 7, Lines 21-31 and Page 8, Lines 4-12):

- "The references in combination would not allow one of skill in the art to arrive at the instantly claimed invention";
- "The equivalency must be recognized in the prior art and can not be based on the mere fact that the components at issue are functional or mechanical equivalents";
- "The mere fact that the cells are collected on filters or in capillaries in the devices does not suggest that their equivalency is recognized in the prior art"; and
- Neither of the references alone or in combination can overcome the deficiencies of the '530 patent."

Teachings from Scholin et al., have been discussed *supra* at item 8. Scholin et al., are silent regarding the automated analysis of the samples collected in said microcosm through spectrometry of a biological sample and DNA fingerprinting by mass spectrometric method (i.e., MALDI-TOF). Scholin et al., however, clearly teach a capillary microcosm wherein said microcosm is a filter, said filter being constituted of array of capillaries by very structure of said filter per discussion *supra*, especially in the light of EXHIBIT 1 and the pertinent art. An artisan of skill applying the broadest meaning of instantly claimed invention drawn to a method as presented in Claims 11-13

The discrepancies outlined above for which Scholin et al., are silent are taught by Koster et al., who teach fully automated modular analytical systems with integrated instrumentation for analysis of biopolymer samples, such as nucleic acids, proteins, peptides and carbohydrates. Analytical methods of detection and analysis, such as mass spectrometry, radiolabeling, mass

tags, chemical tags and fluorescence chemiluminescence, are integrated with robotic technology and automated chemical reaction systems to provide a high-throughput, accurate Automated Process Line (i.e., APL (Abstract, Lines 1-9). Koster et al., further teach methods for automated analysis of biopolymers using the integrated APL system. In preferred embodiments, provided are automated methods for preparing a biological sample for analysis; introducing the sample into an analytical instrument; recording sample data; automatically processing and interpreting the data; and storing the data in a bioinformatics database. In a particular embodiment, patient DNA samples are automatically analyzed to determine genotype (Column 2, Line 61 to Column 3, Line 2). Isola et al., teach MALDI-TOF mass spectrometry to measure the molecular weights of different DNA probes. Total genomic DNA of bacteriophages bound to charge-modified nylon membranes was identified by the hybridization of species-specific oligonucleotide probes. Isola et al., further teach detection of hybridizations with multiple probes with MALDI-TOF mass spectrometry. Isola et al., also demonstrate that multiple-probe hybridization can be very sensitively resolved by mass spectrometry. Six probes different mass tag were used for hybridization on a spot. MALDI-TOF mass spectrometry was successfully used to measure these probes simultaneously (Abstract, Lines 14-22).

Thus, contrary to the assertions made in the response filed 16 March 2010, a person of ordinary skill in the art at the time the invention was made would have been motivated to combine teachings from Scholin et al., in view of Koster et al., and further in view of Isola et al., to obtain a method to characterize cells in an environment, said method comprising the steps of collecting a sample in capillary microcosms through an automated device and subsequently processing the samples by subjecting them to mass spectrometry (i.e., MS) analysis, wherein MS is MALDI-TOF, and a cell lysate is analyzed for determining at least one molecular weight in comparison to a library of molecular weights for determining a turn-over rate of a particular isotopically labeled compound; because Koster et al., teach a method to analyze patient DNA samples in an integrated instrumentation for analysis of biopolymer samples, such as nucleic acids, proteins, peptides and carbohydrates employing analytical methods of detection and analysis, such as mass spectrometry, radiolabeling, mass tags, chemical tags and fluorescence chemiluminescence that are integrated with robotic technology and Isola et al., teach MALDI-TOF mass spectrometry to measure the molecular weights of different DNA probes. Thus, each of Koster et al., and Isola et al., remedy the deficiencies in teachings from Scholin et al., of automated analysis of biopolymer samples, such as nucleic acids, proteins, peptides and

carbohydrates employing analytical methods of detection and analysis, such as mass spectrometry, radiolabeling, mass tags, chemical tags and fluorescence chemiluminescence and of applying MALDI-TOF to measure molecular weights. Please note that measuring of DNA molecular weights and other techniques that Koster et al., teach would automatically give the turnover rate of a compound of interest.

Furthermore, contrary to the argument regarding equivalency, the rejection of Claims 11-18 and 21-22 under 35 U.S.C. §103 (a) as obvious over combined teachings from Scholin et al., in view of Kosher et al., and further in view of Isola et al., in the Office Action mailed 17 September 2009 has not been made on the basis of doctrine of equivalence (See, Office Action mailed 17 September 2009, Pages 3-5, item 9). Additionally, contrary to arguments presented in the response filed 16 March 2010, per discussion presented *supra*, the invention claimed in Claims 11-18, 21-22 and newly presented Claim 50 is obvious under 35 U.S.C. §103 (a) over combined teachings from Scholin et al., in view of Kosher et al., and further in view of Isola et al.

The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art at the time the invention was made. See *In re Keller* 642. F. 2d 413, 208 USPQ 871 (CCPA 1981). Note that although each of the Examiner-cited references by themselves may not teach every component in the same order or manner as claimed in the claims under prosecution in the instant application, these references are not relied upon exclusively but in combination. Furthermore, the 35 U.S.C. §103 statute does not require that the prior art identically disclose or describe Applicants' invention but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time the invention was made. In this case, given the teachings from each one of Scholin et al., as discussed in item 8 *supra*, Kosher et al., and Isola et al., the claimed invention would have been obvious to a person of ordinary skill at the time the claimed invention was made.

Furthermore, a rejection under 35 U.S.C. §103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to Applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's arguments cited *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at pages 3-5, item 9 of the Office Action mailed 17 September 2009 and for the additional reasons as discussed and explained in the preceding paragraphs. Therefore, rejection of Claims 11-18, 21-22 and 50 under 35 U.S.C. §103 (a) as obvious over combined teachings from Scholin et al., (US Patent 6,187,530 B1, Applicants' IDS item AB) in view of Kosher et al. (US Patent 6,730,517 B1) and further in view of Isola et al (1997. MALDI-TOF Mass Spectrometric Method for Detection of Hybridized DNA oligomers. Analytical Chemistry, Volume 73, Pages 2126-2131, Applicants' IDS, item CB) in the Office Action mailed 17 September 2009 is maintained and adhered to.

Conclusion

10. Claims 19-20 are objected to as being dependent upon a rejected base claim (i.e. Claim 15), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. No Claims are allowed.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657

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13 June 2010

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